WO 2005/050214 PCT/EP2004/011958

35

Claims:

5

15

20

30

 A method of predicting whether an individual having hepatitis B virus (HBV) infection will respond to interferon (IFN) treatment; the method comprising;

determining the presence or absence of antibodies reactive with a preS1(94-117) peptide in a sample obtained from the individual,

the presence of said antibodies in said sample being indicative that said individual will respond to said treatment.

- 2. A method according to claim 1 comprising detecting the presence of said antibodies in said sample and thereby determining that the individual will respond to IFN treatment
- 3. A method according to claim 1 comprising detecting the absence of said antibodies in said sample and thereby determining that the individual will not respond to IFN treatment
- 4. A method according to any one of the preceding claims wherein the individual has chronic HBV infection.
- 25 5. A method according to any one of the preceding claims wherein the individual is HBeAg positive.
 - 6. A method according to any one of claims 1 to 4 wherein the individual is HBeAg negative.
 - 7. A method according to any one of the preceding claims wherein the antibodies are IgG or IgM antibodies.

WO 2005/050214 PCT/EP2004/011958

36

.8. A method according to any one of the preceding claims wherein the sample is a blood, serum or plasma sample.

9. A method according to any one of the preceding claims comprising;

contacting the sample with a preS1(94-117) peptide and; determining binding of said antibodies to said peptide.

- 10. A method according to claim 9 wherein the peptide
 10 comprises a detectable label.
 - 11. A method according to claim 9 wherein said peptide is immobilised.
- 15 12. A method according to any one of claims 9 to 11 wherein said binding is detected with a labelled secondary antibody.
- 13. A kit for use in predicting whether an individual having hepatitis B will respond to interferon (IFN) treatment, the 20 kit comprising;
 - a preS1(94-117) peptide.

5

25

- 14. A kit according to claim 13 wherein said peptide is immobilised on a solid support.
- 15. A kit according to claim 14 wherein the solid support is a microtitre plate.
- 16. A kit according to any one of claims 13 to 15 further
 30 comprising a labelled secondary antibody which binds to human antibodies.

WO 2005/050214 PCT/EP2004/011958

37

- 17. A kit according to any one of claims 13-16 further comprising regents for detecting the binding of the labelled secondary antibody
- 5 18. A kit according to any one of claims 13-17 further comprising wash buffers.
 - 19. A kit according to any one of claims 13-18 further comprising sample-handling containers.
- 20. A method of treating a hepatitis B infection in an individual comprising;

10

15

20

identifying the individual as responsive to interferon (IFN) treatment using a method according to any one of claims 1 to 12, and;

administering IFN to said individual.

- 21. A method according to claim 20 wherein the IFN is alpha-IFN.
- 22. A method according to claim 20 or claim 21 wherein corticosteroid is administered to the individual.
- 23. A method of predicting whether an individual having
 25 hepatitis B virus (HBV) infection will respond to interferon
 (IFN) treatment which is substantially as described herein,
 with reference to the accompanying table and figures.